

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

REMARKS

This Amendment is being filed concurrently with an RCE.

The Office Action mailed September 11, 2007, has been carefully reviewed and, to facilitate prosecution, Applicants requested a personal interview which was conducted by Examiner Hand on February 11, 2008. Applicants were represented by Suzin Bailey. Applicants sincerely thank Examiner Hand for her time and cordiality in conducting the interview.

During the interview, the prior art reference of WO 98/53771 to Nielsen et al. ("WO Nielsen") was discussed, as well as a related U.S. application, Publication No. US 2003/0004477 to Nielsen et al. ("Nielsen"). Applicants presented a prototype of an ostomy appliance body side member having an adhesive wafer with two adhesive surfaces of different materials on the upper and lower surfaces in accordance with the claimed invention. The structural features of the second adhesive layer on the upper surface of the wafer as demonstrated were discussed in conjunction with Figure 2 of the specification. Further substance of the interview is incorporated in the following remarks provided in response to the Office Action.

By this Amendment, Applicants have canceled claim 38, amended claims 37, 40, 41, 48, 50 and 51, and added claims 52-59.

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Claims 37 and 39-59 are pending in the application. Claims 37, 48, 50 and 51 are independent.

As an initial matter, Applicants have corrected informalities noted in the specification.

The Examiner rejected claims 37-51 under 35 U.S.C. 102(b) as being anticipated by WO Nielsen.

As discussed during the interview and as set forth in amended claims 37, 48, 50 and 51, the present invention is directed to an adhesive wafer or sealing member having an inner rim defining a hole for accommodating a stoma, a first adhesive surface to adhere to the skin and a second surface facing away from the user that is provided with a hydrophobic adhesive layer having an adhesive upper surface that is different from but compatible with the first adhesive surface. The wafer or sealing member is configured to allow the stoma-accommodating hole to be enlarged by rolling up the inner rim of the hole to form a torus. The torus is locked in this rolled up position through the adherence of the first adhesive surface and the hydrophobic adhesive on the adhesive upper surface of the wafer second surface.

The hydrophobic adhesive ensures that the torus will not unroll even when the first adhesive surface is exposed to moisture. This is important because the first adhesive surface is typically a moisture absorbing adhesive and therefore susceptible to losing

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its adhesive tack in the presence of moisture. Without the hydrophobic adhesive on the second surface, this loss of adhesive tack will allow the torus to unroll, creating a risk of injury or constriction of the stoma. The addition of a second, hydrophobic, adhesive layer having an *adhesive upper surface* is not shown by WO Nielsen and, in fact, is contrary to the teaching thereof.

WO Nielsen discloses an ostomy appliance having an adhesive wafer and a separate sealing member for sealing around the stoma. The sealing member includes an adhesive layer 7 which is covered on the non-skin-facing surface, i.e., the side facing the bag, with a film layer 14. The film layer 14 is not adhesive on the side facing away from the user but instead is explicitly stated to be configured so as to "*prevent a tacky surface on the side facing the bag*" (emphasis added) (see page 8, lines 12-13; page 13, line 20; page 14, lines 9-11). WO Nielsen discloses PARAFILM, a flexible thermoplastic sheet material, as a possible embodiment for the backing layer (see page 8, line 10).

During the interview, Applicants discussed with the Examiner the sentence following the above quoted phrase of WO Nielsen as it appears on page 8 where, at lines 13-14, it is stated that, "The mouldable backing stretches out beyond the outer periphery of the ring in the form of a flange or adhesive layer."

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(Emphasis added). Examiner Hand expressed her view that describing the backing as an "adhesive layer" seems to contradict the preceding statement that the backing prevents a tacky surface. She also presented two web page printouts describing the characteristics of PARAFILM; a copy of these printouts is attached for the record.

Applicants maintain that the description of the backing as stretching beyond the ring periphery in the form of "an adhesive layer" was not intended and does not describe the *upper surface* of the backing layer. Were the *upper surface* being described, the specific provision that appears on each of pages 8, 13 and 14 as identified above, i.e., that the side of the wafer facing the bag must not have a tacky surface would be meaningless. Instead, the *bottom surface* of the backing layer may be adhesive in order to enhance the adherence of the backing layer to the wafer.

Accordingly, in that WO Nielsen does not disclose a second adhesive layer on the top side of the wafer having an adhesive *upper surface*, and in fact teaches explicitly against a tacky surface on the top side of the wafer, claims 37, 48, 50 and 51 are patentable over Nielsen. Claims 39-47, 49 and 52-59 are also in condition for allowance as claims properly dependent on an allowable base claim.

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Further, claims 52-59 are separately patentable for the subject matter contained therein. First, WO Nielsen does not teach or suggest that the wafer has an adhesive upper surface that is protected by a release liner which is removed prior to forming a torus around the stoma, as provided in claims 52 and 56. Instead, the backing layer in WO Nielsen remains in place at all times during use of the wafer.

Second, WO Nielsen does not disclose that the release liner covering the adhesive upper surface is embodied as a separator sheet that is covered by the carrier sheet, with the carrier sheet having a weakening zone that defines a central part of carrier sheet positioned over the separator sheet which is separately removable so that the separator sheet can be removed to expose the adhesive upper surface while a remainder of the carrier sheet remains in place, as provided in claims 53 and 57.

Third, WO Nielsen does not show that an outer edge of the separator sheet extends under the inner rim of the carrier sheet, with the separator sheet including a weakening zone that defines a central part which can be removed separately while the outer edge of the separator sheet outer edge remains in place under the carrier sheet inner rim, as stated in claims 54 and 58.

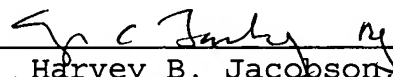
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Finally, WO Nielsen does not teach or suggest that the aforesaid weakening zones are defined by cuts in the carrier and separator sheets as provided in claims 55 and 59.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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HBJ/SCB

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Parafilm® M Barrier Film



Flexible, Moldable, Self-sealing Barrier to Moisture Loss



Chinese



Spanish



Parafilm® M and Dispenser

Parafilm® M is a unique self-sealing, moldable and flexible film for numerous uses in the typical laboratory including the typical electron microscope laboratory. Parafilm® M has unique permeability properties, impressive water vapor transport properties, and is resistant to many common reagents. With the use of the special Parafilm® M dispenser, which are sized to take either the 2" (50.8 mm) or 4" (101.6 mm) wide rolls, one can conveniently cut off uniform sized strips or squares of 2" (50.8 mm) length. The thickness of all Parafilm products is 0.005" (127µm) and although we are often asked about the availability of some other thickness, there is, at this time, no possibility for the making of the product in any other thickness. Another novel characteristic of Parafilm is the ease with which one can make a "dead fold". And as if this is not enough, Parafilm can be stretched 3 to 4 times its original length before breaking.

Parafilm:

A whole family of products Parafilm M laboratory sealing film has become so successful worldwide that new products have been introduced for specific markets such as Parafilm Budding (Grafting) Tape, Parafilm® Florist Stem Wrap, and Floratape®. A comparison between these different Parafilm products can be understood in a very short time period.

Laboratory:

Parafilm® is ideal for the scientific laboratory because it is a thermoplastic, self-sealing film. It holds moisture loss to a minimum. And it offers excellent protection for the contents of broth tubes, flasks,

culture tubes and petri dishes. The unique properties of the film enable it to cling around even irregular shapes and convoluted surfaces. Even a flask falling off need not necessarily result in a terrible spill and clean-up. Assuming it has been sealed properly with Parafilm[®] M, the liquid contents are protected against spillage and contamination and/or evaporation.

Microscopy Laboratory:

Protect the contents of tubes, flasks and petri dishes from moisture loss with flexible, moldable Parafilm[®] M the self-sealing, odorless, colorless, semi-transparent thermoplastic film that molds easily around the top of lab containers. Permeable by oxygen and CO₂. Parafilm M[®] is ideal for many lab applications. **For electron microscopy**, use for picking up floating grids and films from liquid surfaces.



Special unique to TEM application:

Parafilm[®] M makes the perfectly hydrophobic surface for transferring small amounts of reagent to a TEM grid. Dispense a single drop of reagent onto the Parafilm surface, it will form a nice non-spreading "bead" against which a grid can be "touched" to the liquid, picking up a controlled amount of liquid by the grid. Especially useful where expensive reagents are involved.

Hospitals:

Parafilm[®] M makes a superior bandage cover in drainage cases. It is useful in all hospital laboratories and medical stocking areas. It is ideal when used as a tray and shelf liner to prevent slippage and breakage of bottles, containers, and instruments. Parafilm M can also be sterilized using either radiation techniques or hydrogen peroxide. But no claims are made about Parafilm being a sterile product in its as received state.



Gardening and Horticulture:

Parafilm is a unique budding tape. It forms excellent seals to the wound and protects the scion bud from rain, dust, and fog. Perhaps of even greater importance it helps to prevent the loss of moisture and the bud from drying out. Note: Consider the newest version of Parafilm for use as a budding tape.

Masking applications:

Parafilm will conform to any surface and fill in the tightest corners. It comes up easily and leaves no residue behind on the surface being protected. It is the preferred material by many for model masking. To use in this application, the as-received Parafilm[®] M is a waxy-rubbery thin substance with a release paper backing. The recommended procedure is to cut out a thin strip from either the 2" or 4" rolls and slowly stretch to about four times its original length and let it set for about one minute. This permits it to stress relax resulting in the development of a nice "tackiness" to the stretched material. This is when the thin strip is applied to the surface requiring protection and masking. Use normal finger pressure to massage it into a good adhesive situation with regard to the substrate surface. After painting, it will come back up with the gentle lift of a toothpick. And unlike a number of other masking agents, it will absolutely not leave behind a residue on the protected surface.

House plants:

Many applications for innovative activities involving house and other indoor plants.

Horticulture and general agriculture:

There has been a recent increase in the use of Parafilm M to seal the stems of certain agricultural products such as for "organic" bananas after they are cut from the plant to protect it from fungus since fungicides can not be used on products being grown under the "organic" designation.

**Availability of "bulk" Parafilm:**

We are sometimes asked about purchasing the waxy resin, not on already processed rolls of material but in some kind of bulk form. And the answer is simply that the product is available in the below listed four formats of the product and the manufacturing operation is such that no other sizes can be considered. Another question has to do with what is a good solvent for Parafilm so that some quantity could be dissolved. And we recommend chloroform as the best solvent for Parafilm. Ethyl ether would also work but it is even more hazardous if not also explosive. However, even for the use of chloroform, strict precautions must be taken in order to prevent exposure to the vapors.

Government Approvals:

Parafilm has never been tested, to our knowledge, for use with food and it does not have any approval for such use from the US FDA (Food and Drug Administration). We are not aware of anything in the composition of Parafilm that would be a hazard for food use, but we want to make the point that no such approval has been given for such use. For Europe, the equivalent statement is a bit more complicated. There have been a few reports of evidence that low levels of certain phytotoxins can be released at low levels, specifically butylated hydroxytoluene (BHT). Now having said all of that, we are told by the manufacturer that all materials used in the formulation of Parafilm M have been approved for direct food contact and in some materials, can actually qualify as food additives.

It is always nice to hear that there can be new markets we can reach by providing more information. Our problem is that the only protection we have from being duplicated are trade secrets surrounding Parafilm-M. To go down the road of laying out the nature of all the impurities chips away at this protection. In my opinion, the best way to approach the purity question is that all the materials in Parafilm-M have been approved for direct food contact and some cases qualify as additives for foods. There may be cases where information can be disclosed under an secrecy agreement, but this must be taken up on a case by case basis.

Dielectric properties:

We are unaware of any data on the dielectric permittivity of Parafilm® M. But since we do get asked this question from time to time, we would say that based on its composition, we would expect it to be similar to that of polyethylene, which has a dielectric constant of about 2.2

Temperature vs. properties:

At temperatures above 38°C, Parafilm starts to degrade and may become difficult to unroll. Signs of degradation could be the film becoming too sticky and unable to be stretched to the desired amount without breaking. Storing Parafilm at up to 49°C for short periods can be tolerated but is not recommended. But we really can't cite a specific temperature where it just can not be used any longer. The particular temperature that would apply in a specific instance would be dependent on the area being sealed and the liquid being heated in the underlying vessel. If higher temperatures are required, we would suggest that DuraSeal™ Laboratory Sealing Film be considered.

The lower temperature range of use depends on the mechanical abuse the Parafilm must endure. It can be put into liquid nitrogen without any problems so long as the Parafilm is not flexed. Like most other plastic materials, we must deal with a brittle material under dry ice and liquid nitrogen conditions. After a liquid nitrogen exposure, Parafilm will recover to normal properties when it is returned to room temperature.

Optical properties:

Parafilm M is optically translucent in the visible range. For UV exposure, we can provide a UV transmittance curve.

Do not use near open flame!

Although Parafilm® M is a unique "waxy" material, it is nevertheless, not too different from candle wax, and is therefore flammable. It should not be used near open flames such as a bunsen burner.





Shelf life:



Parafilm® M is quite inert, but nothing of an organic nature lasts "forever". One can expect three years without deterioration of the unique properties of Parafilm provided it is stored between 7°C and 32°C and at 50% relative humidity.

Physical properties





Pre-cut rolls

Size	SPI #	Each		In Stock
2" (5.1 cm) x 250 ft (76.2 meters)	01851-AB	\$ 20.80	 ADD TO CART	Yes
2" (5.1 cm) x 250 ft (76.2 meters) case of 24 rolls <u>Not eligible for flat rate shipping programs</u>	01851-CA	474.09	 ADD TO CART	Yes
4" (10.2 cm) x 250 ft (76.2 meters)	01852-AB	34.12	 ADD TO CART	Yes
4" (10.2 cm) x 250 ft (76.2 meters) case of 12 rolls <u>Not eligible for flat rate shipping programs</u>	01852-BC	392.21	 ADD TO CART	Yes

4" (10.2 cm) x 125 ft (38.1 meters)	01853-AB	21.79	 ADD TO CART	Yes
4" (10.2 cm) x 125 ft (38.1 meters) case of 12 rolls <u>Not eligible for flat rate shipping programs</u>	01853-BC	249.02	 ADD TO CART	Yes

Single large sheet

20" x 50' (50.8 x 1524 cm) rolled in tube	01854-AB	57.53	 ADD TO CART	Yes
20" x 50' (50.8 x 1524 cm) rolled in tube case of 6 rolls <u>Not eligible for flat rate shipping programs</u>	01854-AG	249.91	 ADD TO CART	Yes

Storage conditions: Room temperature
Non-hazardous from stand point of shipping

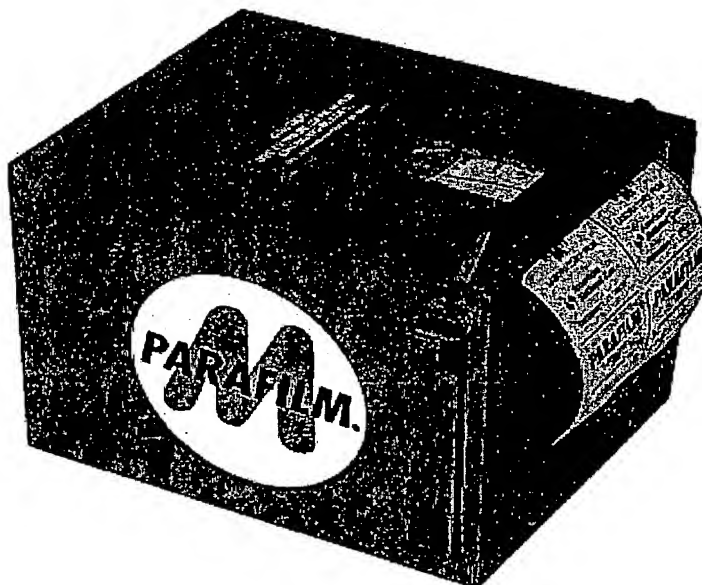
Dispensers:


Pre-cut rolls:

(25.4 mm) and 4" (100.8 mm) wide rolls fast , safe, and easy, make possible with the smooth downward lever action. The recessed blade ensures safe, dependable use and simplified replacement. The automatic lever holds the desired cut-off length in place adding stability while dispensing.



Use
Instructions



	SPI #	Each		In Stock
Cutter/Dispenser for above pre-cut rolls	01855-AB	42.84	 ADD TO CART	Yes

Parafilm M[®] Laboratory Sealing Film



Physical properties



Parafilm M[®] is a semi-transparent, flexible thermoplastic, and in its final form is a highly water proof and water resistant sheet material. It is practically colorless, odorless, tasteless and approximately 0.005" (e.g. 5 mils/ 127 μ m) in thickness. The density of the film is reported to be 0.992.

The unique properties of Parafilm M[®] make it ideal and adaptable for many important laboratory uses and techniques. It molds and seals itself tightly around test tubes, flasks, and various instruments and objects with irregular surfaces. The actual composition of Parafilm M is not actually released by the manufacturer, now ever it is described as being a "blend of olefin-type materials". From our own experience using the product quite extensively in our own laboratory environment, we have generally perceived it to be close in description to that of a very low molecular weight polyethyelene with perhaps some additional wax like materials. That is our own interpretation of its composition and not that of the manufacturer. In any case, the maximum use temperature seems to be on the order of 54° C/130° F which happens to be very consistent with the composition of the material to which is described by the manufacturer and also our own independent perception of its composition. We know that the film becomes soft and sticky at about 130 - 150°F (55-66°C).

In electron microscopy and histology laboratory environments, it is useful for wrapping around, as a final kind of seal, any flask or container containing glutaraldehyde, aqueous osmium solution, just to name a few of its many applications in that kind of environment. Remember, for osmium and glut, it was not meant to be the *only* seal, it is mean to be a back up seal, just one more precaution to take in the event the primary seal (e.g. the ground glass cap) should somehow become dislodged and open up and/or fail.

It is highly insensitive to moisture vapor, moisture loss, and moisture absorption and yet permeable to gasses sufficiently to make it ideal for working with culture media. This property has also made it adaptable and ideal as an "overwrap" for wet bandage and covers in the drainage cases.

The specific gravity of Parafilm M[®] is 0.922. There is a test done on coal for determining its BTU value and Parafilm M[®] is used in the protocol and in order to make the correct calculations, the specific gravity of the material is needed.

ON-LINE [To Ask a Question or Make a Comment](#)





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Monday February 11, 2008

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